

PATENT COOPERATION TREATY

PCT Rec'd PCT/PTO 03 OCT 2005

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

10/551764

(PCT Rule 44bis)

Applicant's or agent's file reference PCA40216-HMY	FOR FURTHER ACTION		See item 4 below
International application No. PCT/KR2004/000781	International filing date (<i>day/month/year</i>) 03 April 2004 (03.04.2004)	Priority date (<i>day/month/year</i>) 03 April 2003 (03.04.2003)	
International Patent Classification (IPC) or national classification and IPC 7 C07K 1/113, 19/00			
Applicant HANMI PHARM. CO. LTD.			

<p>1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.</p>																
<p>3. This report contains indications relating to the following items:</p> <table> <tr> <td><input checked="" type="checkbox"/> Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/> Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/> Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/> Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/> Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/> Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table> <p>4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).</p>	<input checked="" type="checkbox"/> Box No. I	Basis of the report	<input type="checkbox"/> Box No. II	Priority	<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/> Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input checked="" type="checkbox"/> Box No. VI	Certain documents cited	<input type="checkbox"/> Box No. VII	Certain defects in the international application	<input type="checkbox"/> Box No. VIII	Certain observations on the international application
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	Date of issuance of this report 14 October 2005 (14.10.2005)
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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

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19th Fl., KEC Building, #275-7, Yangjae-dong, Seocho-ku
Seoul 137-130 Republic of Korea

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RECEIVED
12 JUL 2004

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) 01 JULY 2004 (01.07.2004)

Applicant's or agent's file reference
PCA40216-HMY

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/KR2004/000781

International filing date (day/month/year)
03 APRIL 2004 (03.04.2004)

Priority date(day/month/year)
03 APRIL 2003 (03.04.2003)

International Patent Classification (IPC) or both national classification and IPC
IPC7 C07K 1/113, C07K 19/00

Applicant

HANMI PHARM. CO., LTD. et al

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.
For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/KR



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Authorized officer

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/KR2004/000781

Box No. 1 Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/KR2004/000781

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-12	YES
	Claims	none	NO
Inventive step (IS)	Claims	1-12	YES
	Claims	none	NO
Industrial applicability (IA)	Claims	1-12	YES
	Claims	none	NO

2. Citations and explanations :

The following documents are cited in the International Search Report;

D1 : US 6,106,828 (Novo Nordisk A/S) 22 Aug. 2000

D2 : US 4,179,337 (Frank F. Davis et al.) 18. Dec.1979

D3 : Pharmaceutical Research, Vol. 16, 1999, pages 813-818, Lee et al.,

D3 : Biological & Pharmaceutical Bulletin, Vol.26, 2001, pages 666-670, Li et al.

D1 discloses polypeptide conjugate with reduced respiratory allergenicity comprising a polymeric carrier having two or more polypeptide molecules coupled thereto and polymeric carrier can be PEG.

D2 discloses polypeptide conjugated with PEG has longer half-life than unconjugated one.

D3 discloses the effect of PEGylation site on half-life. It reveals that mono-PEGylated salmon calcitonin at Lys18 residue has about 450 times longer half-life than native salmon calcitonin.

D4 discloses PEGylated human TNF alpha has longer half-life than unconjugated one.

The documents set forth above do not suggest or explicitly disclose polypeptide conjugate comprising two or more polypeptide coupled with polymeric carrier and each polypeptide is modified with one PEG. In addition, a skilled person in the art is not believed to invent the present invention easily by combination of the teachings of D1 to D4.

Therefore, Claims 1-12 of the present invention are novel and involve an inventive step.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/KR2004/000781

Box No. VI Certain documents cited

1. Certain published documents (Rule 43bis.1 and 70.10)

<u>Application No. Patent No.</u>	<u>Publication date (day/month/year)</u>	<u>Filing date (day/month/year)</u>	<u>Priority date (valid claim) (day/month/year)</u>
US 4,179,337	18/12/1979	28/07/1977	
US 6,106,828	22/08/2000	28/07/1998	

2. Non-written disclosures (Rule 43bis.1 and 70.9)

Kind of non-written disclosure

Date of non-written disclosure
(day/month/year)

Date of written disclosure
referring to non-written disclosure
(day/month/year)